



IFW

Attorney Docket No.: VOS-14 CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Not yet assigned  
Group Art Unit : 1645  
Applicants : Leszek Wojnowski et al.  
Application No. : 10/607,596 Confirmation No.: 4858  
Filed : June 27, 2003  
For : IDENTIFICATION OF THE GENETIC DETERMINANTS OF  
THE POLYMORPHIC CYP3A5 EXPRESSION

New York, New York  
March 3, 2005

**Mail Stop: Amendment**  
Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

Transmitted herewith is: [X] a Supplemental Information Disclosure Statement (in duplicate); [X] Form SB/08; and [X] copies of cited references to be filed in the above-identified patent application.

The enclosed Supplemental Information Disclosure Statement is being submitted more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97(b)(3), applicant believes that submission of this Supplemental Information Disclosure Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in

connection with this Supplemental Information Disclosure Statement to Deposit Account  
No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

Jane T. Gunnison  
James F. Haley, Jr. (Reg. No. 27,794)  
Jane T. Gunnison (Reg. No. 38,479)  
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Andrew Shive  
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Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants hereby make of record the following documents, copies of which are submitted herewith:\*

Foreign Publications

<u>Publication No.</u>	<u>Publication Date</u>
WO 98/44939	October 15, 1998
WO 00/47771	August 17, 2000

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\* A completed Form SB/08 (submitted in duplicate) listing these documents is attached hereto.


Other References

Hustert, E. et al., "The genetic determinants of the CYP3A5 polymorphism," *Pharmacogenetics* 11:773-779 (2001).

Paulussen, A. et al., "Two linked mutations in transcriptional regulatory elements of the CYP3A5 gene constitute the major genetic determinant of polymorphic activity in humans," *Pharmacogenetics* 10:415-424 (2000).

Applicants respectfully request that the documents be: (1) fully considered by the Examiner during the course of examination of this application; and (2) printed on any patent that may issue from this application. Applicants also request that a copy of the enclosed Form SB/08, duly initialed by the Examiner, be forwarded to the undersigned with the next official communication.

Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27, 794)

Jane T. Gunnison (Reg. No. 38,479)

Attorneys for Applicants

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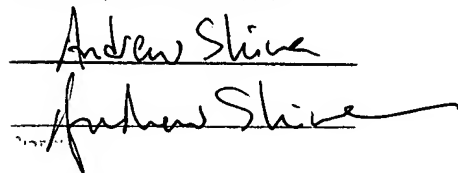
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PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031  
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<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)  Sheet 1 of 1			<b>Complete if known</b>	
			Application Number	10/607,596
			Filing Date	June 27, 2003
			First Named Inventor	Leszek Wojnowski et al.
			Art Unit	1645
			Examiner Name	Not yet assigned
			Attorney Docket Number	VOS-14 CON

U.S. PATENT DOCUMENTS					
Examiner initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>1</sup> - Number <sup>2</sup> - Kind Code <sup>3</sup>				
		WO 98/44939	10/15/1998	Merck & Co, Inc.		
		WO 00/47771	08/17/2000	Genset		

NON PATENT LITERATURE DOCUMENTS			
Examiner initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>6</sup>
		Hustert, E. et al., "The genetic determinants of the CYP3A5 polymorphism," <i>Pharmacogenetics</i> 11:773-779 (2001).	
		Paulussen, A. et al., "Two linked mutations in transcriptional regulatory elements of the CYP3A5 gene constitute the major genetic determinant of polymorphic activity in humans," <i>Pharmacogenetics</i> 10:415-424 (2000).	

Examiner Signature	Date Considered
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All References Have Been Considered: \_\_\_\_\_  
Examiner

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.